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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,477	11/13/2000	Isabelle Preuilh	2365-23	4547
23117	7590	01/18/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			COTTON, ABIGAIL MANDA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/709,477		PREUILH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Abigail M. Cotton		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2005 and 07 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-33, 35-42, 44-48 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-33, 35-42, 44-48 and 50-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 8, 2005, has been entered.

Claims 31-33, 35-42, 44-48 and 50-61 are pending in the application and are being examined on the merits herein.

Applicant's amendments to the claims have overcome the rejections of record made in the Final Office Action mailed on April 8, 2005.

The following new rejections are being made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 37-42, 44-48, 50-51 and 57-61 are rejected under 35 U.S.C. 101(a) as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 in view of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology (of record.)

The instant claimed invention is directed to a composition comprising, in an aqueous medium an active principle selected from a corticoid or a retinoid, an anionic surfactant, an amphoteric surfactant and 0.1 to 25% of a propenetrating agent selected from volatile C1-C4 alcohols and glycol ethers.

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative and other ingredients, wherein the detergent can be combination of sodium lauryl sulfate and cocoamidopropyl betaine. Cameron further teaches that the medicated shampoo is suitable for the

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treatment of scalp disorders such as flaking, scaling, dandruff, seborrhea, eczema and others (see abstract and column 1, line 5 through column 6, line 35, in particular.)

Cameron does not specifically teach the claimed propenetrating agents or the combination of anionic and amphoteric surfactants as recited in the claims.

Hirota teaches a composition for the scalp that is suitable for the treatment of conditions such as dandruff and scalp itching (see abstract, in particular.) Hirota teaches that the composition comprises a polyalkylene glycol monoalkyl ether of formula (I) (see abstract, in particular), such as diethylene glycol monoethyl ether (i.e. ethoxydiglycol as recited in claim 44), and that the component shows beneficial effects when provided in a hair care composition, such as the suppression of dandruff and itching as well as controlling the growth of bacterial flora and maintaining moisture on the scalp (see paragraphs 0008-0009, in particular.) Hirota teaches that an amount of the polyalkylene glycol can be from 0.1 to 5% by weight (see abstract, in particular), which meets the limitation as recited in the claim.

Hirota furthermore teaches that the treatment composition can be formulated with alcohols that are conventionally used in hair cosmetics, such as ethanol as recited in claim 44 (see paragraphs 0023-0024, in particular), and teaches that 10-90% of the ethanol can be provided, which range overlaps with that recited for the propenetrating agent amount recited in claim 1. Thus, Hirota teaches that a scalp treatment

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formulation can comprise the recited propenetrating agents of ethoxydiglycol and ethanol for the treatment of scalp disorders such as dandruff and itching.

The Handbook of Cosmetic Science and Technology teaches that amphoteric surfactants provide foam stabilization in combination with the ability to mitigate irritancy of other materials, such as primary surfactants and, in some cases, will modify product viscosity. They are taught as being compatible with anionic surfactants, wherein anionic surfactants are taught as the primary surfactants. See pages 220-224, in particular.

Accordingly it would have been obvious to one of ordinary skill in the art to provide the ethoxydiglycol of Hirota to the scalp treatment composition of Cameron, because Cameron teaches treating scalp conditions such as dandruff and other conditions associated with itching, such as psoriasis, and Hirota teaches that ethoxydiglycol provides benefits in the treatment of dandruff and itching. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ethoxydiglycol of Hirota in the composition of Cameron with the expectation of forming a scalp treatment composition suitable for the treatment of scalp disorders such as dandruff and psoriasis. It would furthermore have been obvious to provide the ethanol of Hirota in the composition of Cameron, because Hirota teaches that ethanol is an alcohol that is conventionally used as a carrier for hair treatment compositions.

It would furthermore have been obvious to one of ordinary skill in the art at the time the invention was made to provide the composition of Cameron and comprising both the anionic and amphoteric surfactants as claimed because of the expectation of achieving a composition that is more stable and that decreases irritation, as taught by the Handbook of Cosmetic Science and Technology. Accordingly, claims 31-32, 37-42, 44-48 and 57-61 are obvious over the teachings of the references.

While the ratio of anionic to amphoteric surfactant is not specifically taught, and the specific amount of a propenetrating agent that is a volatile C1-C4 alcohol, is also not specifically taught, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Accordingly, claims 50-52 are obvious over the references.

The Examiner respectfully points out that the recitation "foaming" and "for washing and treating the hair and/or scalp" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim 55 is rejected under 35 U.S.C. 103(a) above as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-42, 43-48, 50-51 and 57-61 above, and further in view of U.S. Patent No. 5,378,731 to Andrews et al, issued January 3, 1995.

Cameron, Hirota and the Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-48, 50-51 and 57-61 above, and teach the hair and/or scalp treatment composition as recited in the claims.

The references do not specifically teach that a pH of the composition is between 2 and 9, as recited in claim 55.

Andrews et al. teaches a medicated shampoo for disinfecting, cleansing, conditioning and moisturizing the hair (see abstract, in particular.) Andrews et al. exemplifies such medicated shampoos having a pH of from 3.6 to 3.8 (see column 11, lines 9-44, in particular), which meets the range limitation of claim 55.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the treatment shampoo of Cameron, Hirota and the



Handbook with a pH of 3.6-3.8, as taught by Andrews et al, with the expectation of achieving a cosmetically acceptable formulation that is safe for application to the hair and scalp.

Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) above as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-42, 43-48, 50-51 and 57-61 above, and further in view of U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999.

Cameron, Hirota and The Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-48, 50-51 and 57-61, and teach the claimed hair and/or scalp treatment composition. The references do not teach the specific corticoids and retinoids recited in claims 33, 35 and 36.

Kligman teaches methods of treating inflammatory dermatosis (see abstract, in particular.) Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments or liquids. Further examples

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of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. The retinoids can be natural or synthetic (see column 1, line 19 through column 12, line 20, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the corticoids and retinoids taught by Kligman into the composition of the combined references because of the expectation of success in achieving a composition that exhibits a synergistic effect in treating chronic dermatosis, such as seborrheic dermatitis, atopic dermatitis, contact dermatitis, psoriasis, and others, and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-42, 43-48, 50-51 and 57-61 above, and further in view of U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997.

Cameron, Hirato and The Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-48, 50-51 and 57-61 above, and teach

the claimed composition for the treatment of the hair and/or scalp. The references do not teach the specific cationic polymers and ceramides as recited in claims 52-54 and 56.

Cauwet et al. teaches hair and skin washing and treatment compositions based on ceramide and/or glycoceramide and cationic polymers. The combination of cationic polymer and ceramide and/or glycoceramide provides synergistic detangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guard hydroxypropyltrimmonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition (see column 13, line 1 through column 20, line 65, in particular.)

### ***Response to Arguments***

Applicant's arguments with respect to claims 31-33, 35-42, 44-48 and 50-61 have been considered but are moot in view of the new ground(s) of rejection.

In particular, Applicant's argue that the Andrews reference does not teach providing the claimed propenetrating agents, but instead teaches providing propylene glycol as a viscosity modifier. However, this argument is moot in view of the new

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rejections made over the Hirato reference, which teaches the desirability of providing the claimed propenetrating agents in a scalp and/or hair treatment composition.

Applicants further argue that the composition as claimed provides a surprising and unexpected reduction in lesions due to psoriasis, and refer to the example given on page 27, lines 5-12 of the instant specification. However, it is noted that the example only reports the reduction in scalp erythemas, hyperkeratosis, etc, that occurred over the duration of the treatment, and does not provide any evidence of unexpectedly good results over conventional treatments or over the treatments as taught by the closest prior art. It should be noted that a showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997).

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, U.S. Patent No. 5,653,70 to Robert Vermeer, issued August 5, 1997, teaches that ethanol, isopropanol and ethoxydiglycol are well known solubilizing or clarifying agents that are used in cosmetic compositions (see abstract and column 38, lines 40-56, in particular.) U.S. Patent No. 6,093,745 to

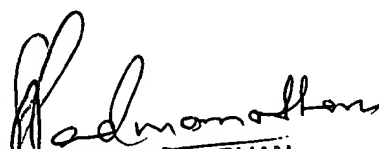
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Hammes et al, issued July 25, 2000 teaches providing skin penetration enhancers for the treatment of psoriasis, such as Transcutol® (ethoxydiglycol). U.S. Patent No. 4,973,468 to Chiang et al, issued November 27, 1990, teaches providing the skin permeation enhancer diethylene glycol monoethyl ether (ethoxydiglycol) to transdermally administer active agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER